

K211765 Cardinal Health RoyalSilk Surgical Gown, Cardinal Health RoyalSilk Scrub Nurse GownNov 23, 2021
168 days to decisionK211765 · Product code: FYA · General Hospital
Source: <https://www.510kdatabase.net/k211765/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Jun 8, 2021
Decision date	Nov 23, 2021
Days to decision	168 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Cardinal Health, LLC
Location	Waukegan, IL, US
Contact	Brenda Gerena
Website	http://www.cardinalhealth.com
510(k) history	2 submissions · 2 cleared · 2021-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211765/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026